



February 16, 2012

Via Courier

David Ashley, Ph.D.
Director, Office of Science
Center for Tobacco Products
Food & Drug Administration
9200 Executive Boulevard
Rockville, MD 20850

RECEIVED

FEB 17 2012

BY: CTP / DCC

LC

Re: Supplemental Information Relating to the Use of Dissolvable Tobacco as an Alternative to Cigarettes or Other Tobacco Products.

Dear Dr. Ashley:

At the meeting of the Tobacco Products Scientific Advisory Committee ("TPSAC") held on July 18-19, 2011, Dr. Curtis Wright IV, the Medical/Clinical Director of our Rock Creek Pharmaceuticals, Inc. subsidiary, presented information on studies conducted to measure the extent to which dissolvable tobacco use resulted in a reduction of the number of cigarettes or other tobacco products consumed by dissolvable tobacco users. In his slide presentation, Dr. Wright noted that the studies conducted to date had reached different conclusions on this issue: some studies suggested a significant reduction in other tobacco use, and other studies suggested no significant difference. (a copy of pages 11 and 14 from Dr. Wrights slide presentation are attached as Appendix "A".) At the January 18-20th TPSAC meetings there was further discussion about the extent to which the referenced studies supported the notion that use of dissolvable tobacco products may result in a reduction of the number of cigarette or other tobacco products consumed by persons who continue to use tobacco products. At the meeting, a number of persons expressed the view that neither those studies nor other evidence support the proposition that dissolvable tobacco product users have or might reduce their other tobacco use.

At the same time, during the public comment portion of the January TPSAC meeting, a number of individuals presented information on their own experience with dissolvable tobacco and other alternative forms of tobacco products. Each presenter recounted that dissolvable tobacco products, or other alternative products, allowed them to significantly reduce their use of cigarettes or other tobacco products and, in several instances, to eliminate any use of cigarettes. Having manufactured dissolvable tobacco products since 2001, our Company has received a number of similar reports provided to us either as unsolicited communications from users of Ariva® or Stonewall®, our Hard Snuff® low-

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TSNA dissolvable products, or as a result of a random survey of Ariva® users conducted in 2002. Because these reports are relevant to the issue of how dissolvable tobacco products are used by consumers who have purchased these products as alternatives to traditional tobacco products, we are including a summary of those reports and related materials with this letter. We are also copying Ms. Caryn Cohn, MS. and providing copies of this letter and the attachments as a written submission for the meeting of the TPSAC tentatively scheduled for March 1st and 2nd.

In 2002 our Company randomly identified 200 Ariva® customers who previously had placed calls to our consumer call center and attempted to contact 167 such callers, to determine if they would participate in a telephone survey. 75 persons eventually participated in the survey and we identified 19 (25%) of those individuals as current users of Ariva®. Of the then-current Ariva® users 16 (84%) responded that they had reduced their cigarette consumption as a result of their use of Ariva®. Six of the then-current Ariva® users (31.6%) stated that they had been able to completely eliminate their use of cigarettes. A copy of the portion of the survey reflecting these results is attached as Appendix "A". (The full survey was submitted to the Center for Tobacco Products in response to its August 2011 request for documents relating to dissolvable tobacco products.)

In the ten-plus years that our Company has been selling its dissolvable tobacco products, we also have received many unsolicited communications from users of Ariva® or Stonewall® regarding their use of our dissolvable tobacco products as a means of reducing cigarette or other tobacco use. We have included as Appendix "C" copies of 58 such communications that we have been able to identify in our files. Many of these communications have previously been submitted to the Center for Tobacco Products in response to requests for information relating to our products. In the attached compilation we have highlighted the portion of the communication relating to other tobacco use and have eliminated or redacted personal identifying information. A sampling of those communications is set forth below:

- (9/15/2002, 4:59 pm) "My friend tried Ariva®. He has been using it for almost five months. His lungs have improved and the coughing and hacking are almost

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gone. He can walk across the pasture where my horses are and now can even ride them. His doctor said she has seen a great improvement in his health.”

- (9/22/2004, 9:49 am) “Although I lapse sometimes, I most certainly have found they cut my intake by at least 50%...I have to be honest though- I still need a fix in the morning and afternoon at work! ...The most impressive result is not lighting up after eating- they really do work!”
- (3/27/2006, 7:00 pm) “I quit a 2 ½ pack a day habit by using this great product. That was two years ago.”
- (10/21/2006, 12:31 am) “I tried your product by taking a chance and ordering it from the catalog that I order my cigarette tobacco from. I had no intention of giving up cigarettes, but after using Stonewall I didn’t feel like smoking anymore. I’ve smoke for 40 years. I haven’t smoked for weeks.”
- (5/2/2007) “She has been using the product to cut down on smoking. She said that since she began using the product she had reduced smoking by 30%.”
- (10/19/2007) “I tried Ariva®. That was two years ago and smoking is absolutely history for me...I am NEVER going to smoke another cigarette... Within a week of quitting, I was off of all the medicines and for the first time in a very long time, I felt like I could breathe. Needless to say, my Doctor is ecstatic about it... And the stigma of smoking has disappeared too... I feel free!”
- (3/11/2008, 5:38 pm) “I continue to be amazed at how well Stonewall® heads off my cravings... I find that it just takes the edge off enough for me to forget about my craving while I really do enjoy the flavor of the wintergreen Stonewalls. This is a very pleasant way to quit smoking.”
- (8/4/2010, 12:58 am) “My friend started taking Ariva® today...I asked him how many cigarettes he had smoked today. He said “7”. I replied, “But that is a lot

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better than 20"...He then said, "The Ariva® helped." To me, a 60%-70% reduction on the first day, with only Ariva, is utterly amazing!"

We believe these communications are significant in that they provide information about the experiences of persons who have chosen to use our products, and about the ability of our products to reduce the use of cigarettes and other tobacco. It is also striking that these communications are very similar to the presentations to the TPSAC during the public comment section of the December 18-20th meeting by individuals who have found dissolvable tobacco products or other alternative products to be effective as a means of reducing cigarette consumption or the use of other tobacco products.

Given the interest at the January TPSAC meeting in the question of whether the use of dissolvable tobacco products has or may result in a reduction in cigarette use or the use of other tobacco products, we request that this letter and the attachments be provided to each of the TPSAC members for their consideration as they continue their mandated review of dissolvable tobacco products.

Sincerely,



Robert E. Pokusa
General Counsel

cc: Caryn Cohn, MS (20-copies)
Paul L. Perito, Esquire (w/o encl.)
Chairman and COO
Curtis Wright, IV (w/o encl.)

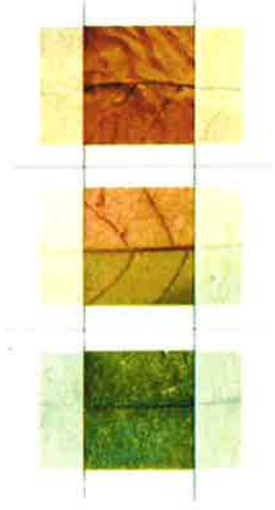
APPENDIX A

Low-Nitrosamine Dissolvable Tobacco Products

Star Scientific, Inc.

Part III

Initiation and Cessation



Using science to reduce tobacco-related harm
at every level of the population

Migration

ARIVA (the smoker's product) is loaded at 1.5 mg nicotine at pH 7.5. STONEWALL (the SLT user's product) is loaded at 4.0 mg nicotine at pH 7.5.

Most light to moderate smokers select ARIVA.

Most heavy smokers and SLT users select STONEWALL.

Usage data suggests most users are using 4-6 lozenges a day.

We do not know how much dual use there is, though the survey data suggest that most dual use is in environments where smoking is prohibited or to avoid exposing others to smoke (work, public places, cars) with significantly fewer cigarettes smoked by users.

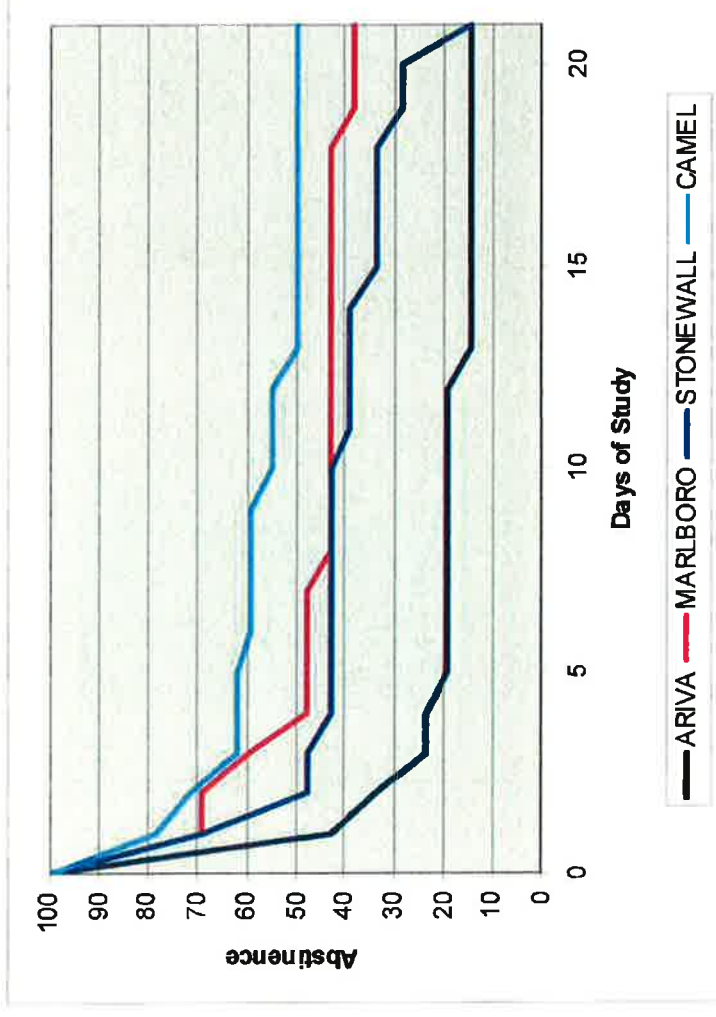
We do not know how many users are successful in cessation using the product, but clearly some are using it to cut down on smoking and some to quit smoking.

The one cessation study reported (Hatsukami 2011) is interesting.

Hatsukami et al. 2011

Hatsukami et al. recruited smokers motivated to quit, allowed them to test four PREPs, then had them attempt cessation using the PREP of their choice. 97 of 135 initially recruited entered the survival phase; selection was roughly equal across three of the PREPS studied (General Snus was not selected by any).

ARIVA was least effective in supporting cessation, with rank order for the rest roughly proportional to mg total CDC nicotine.



ARIVA (1.5) < STONEWALL (4.0) < Marlboro (5.4) < Camel (5.6)

Migration

Two other recent studies involving Star dissolvable tobacco products in populations of smokers not motivated or planning to quit have also provided interesting results related to migration and cessation.

Carpenter and Gray (2010) found that relative to a control group (conventional cigarettes), daily use of ARIVA and STONEWALL for 2 weeks resulted in:

- A statistically significant reduction (40%) in cigarettes smoked per day;
- Significant increases in two measures of readiness to quit in the next month ($p < 0.001$), or within the next six months ($p = 0.04$); and,
- Significant increases in self-efficacy to quit smoking ($p < 0.001$).

Migration

O'Connor et al. (2011) found that smokers not willing to quit may be willing to use an oral smokeless product such as STONEWALL as a substitute for cigarettes, but did not quit completely (suggesting dual use with fewer cigarettes smoked in this population).

The same was true for the NRT comparator used in this study, Commit lozenge.

Results showed:

- A statistically significant reduction (25%) in cigarettes per day
- Exhaled CO decreased significantly (10%) from before to after trial
- Salivary cotinine was stable

Smokers smoked less, and compensated for nicotine needs with the reduced toxin content oral products.

APPENDIX B

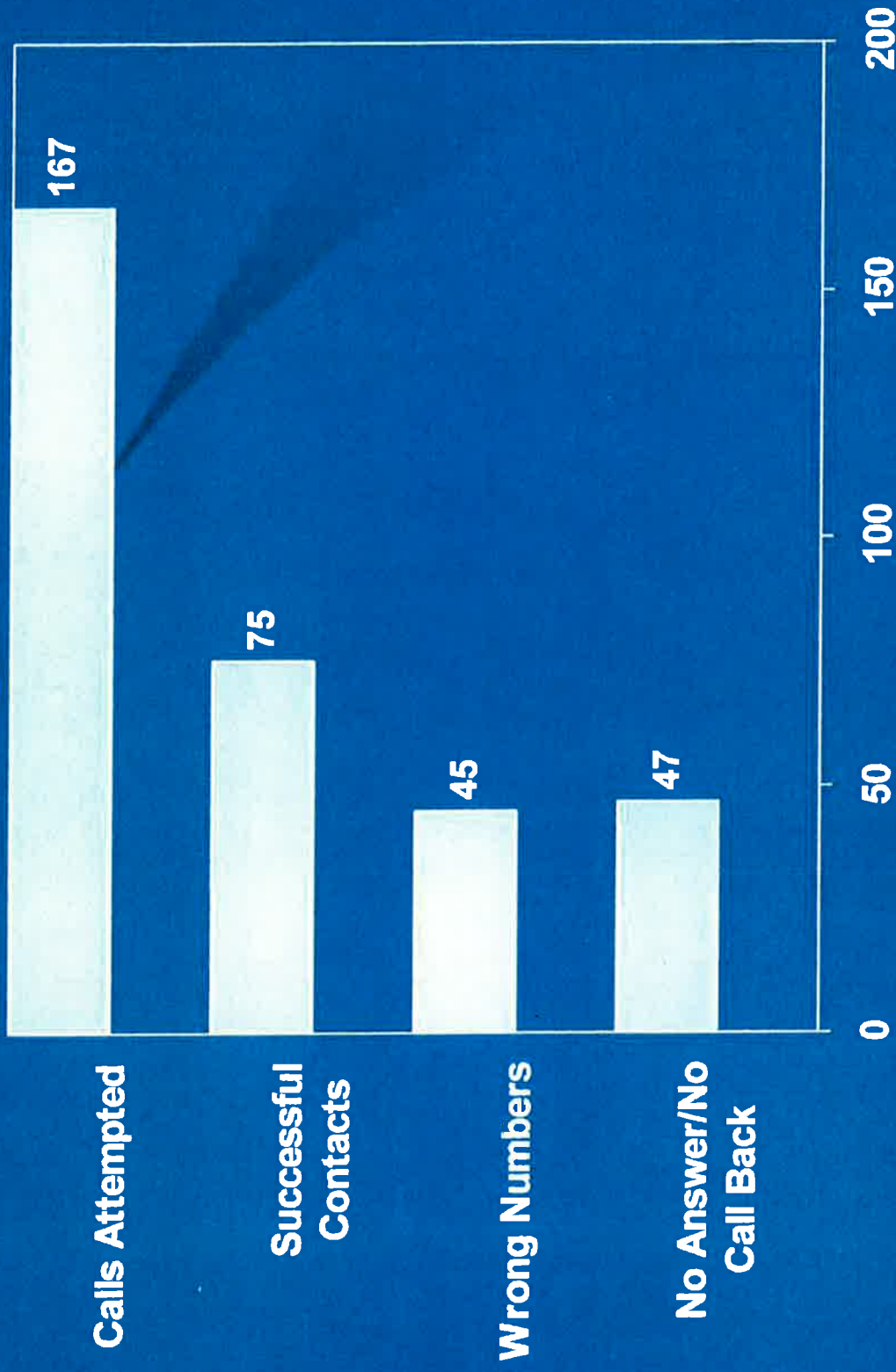
**FOLLOW-UP RANDOM SURVEY
OF GO-ARIVA™ CALLERS
OCTOBER 2002**

Survey Methodology

- Used database of reports on 892 calls to Go-Ariva consumer line between its inception (3/20/02) and October 16
- Identified all calls related to:
 - Where Ariva could be purchased
 - Nicotine content in the product
 - Other general information about product
 - Consumer feedback
- Every third call within these parameters selected at random

- Random selection yielded 501 callers within selected parameters
- “Every third” selection yielded 167 callers for follow-up

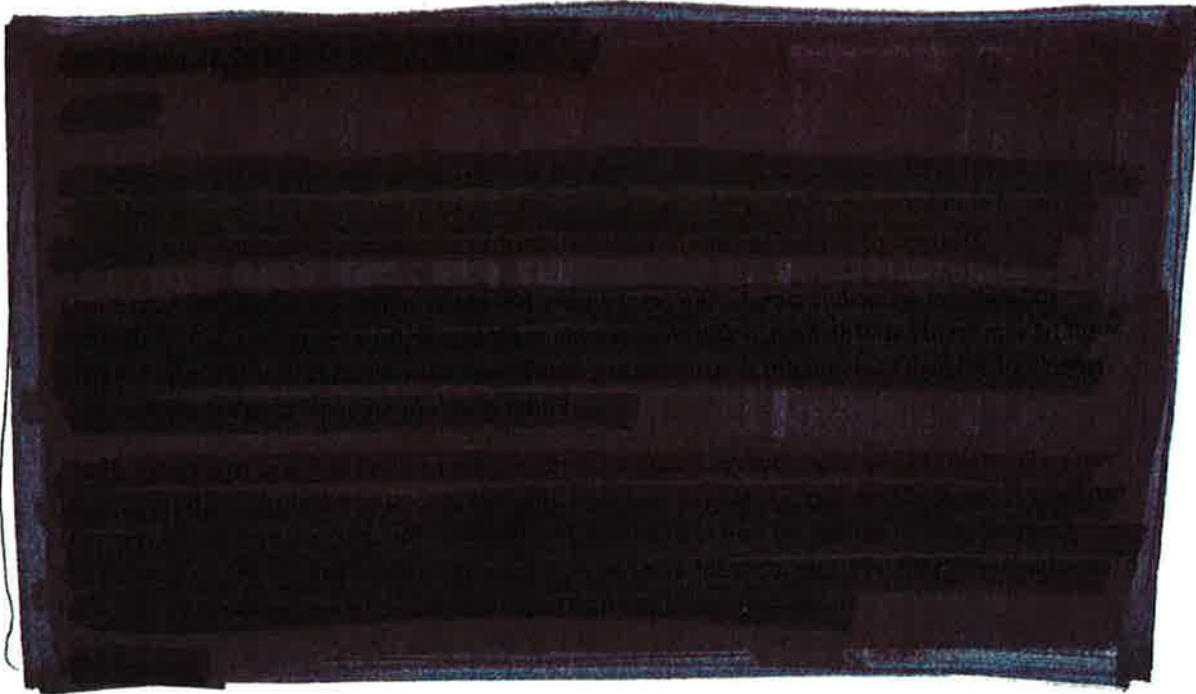
Rate of Success for Calls



Current Ariva™ Users

- **19 (25%) of all callers contacted currently use Ariva**
- **16 (84%) of those current Ariva users said they have decreased their daily cigarette/smokeless use**
- **6 (31.6%) of those current users have completely transitioned from cigarettes to Ariva™**

APPENDIX C



Wed 8/4/2010 12:58 AM

Hello, Sara,

I sent the 6 20-packs of Ariva which the Smoker Friendly shop still carried, to my 66 yr old friend, (b) (6) (b) , in Southern Colorado. He is from Germany, and has been smoking 20 cigarettes per day for 52 years. He was recently diagnosed with metasticized prostate cancer, Stage 3 -and was having an Impossible time for the past 2 months, quitting, as recommended by his doctor.

He had been told to get a month's worth of nicotine patches by his doctor, and had tried them a few times, but they did not help. He was still smoking 20 per day, in spite of the knowledge that he would die more quickly if he continued smoking like this. It was impossible to reduce his habit.

My package arrived yesterday in the mail -(he is now living in the far corner of Southern Colorado on a cattle ranch with is daughter who teaches reining) and does hard labor all day)- and he started taking Ariva today, and has not worn a patch for several days, as they were not helping. I called him tonight, as I do every day.

I asked him how it went. he said "not so great". So I asked him how many cigarettes he had smoked today. he said "7". I replied, "but that is a lot better than 20. Why do you say things are not going so well?" He said "No cigarettes would be better". He is a stoic German, for sure. He then said "The Ariva helped". To me, a 60%-70% reduction on the first day, with only Ariva, not Stonewall, is, to me, utterly amazing!



Sat 10/24/2009 10:34 AM

Hi,

I bought Ariva for use just as you advertise it. I wanted to use it at work when I couldn't smoke. What I found is that it was so satisfying that I really didn't need a cigarette.

I then thought that I could just use these for a few weeks instead of smoking so I could get used to not smoking, and then quit. That's exactly what I did. After 6 weeks of not smoking, I just stopped Ariva cold turkey. Amazingly, I didn't crave a cigarette. Instead I had a mild craving for an Ariva tablet, which I easily overcame.

So, I wasn't seriously considering a quit-smoking attempt at all, but Ariva worked so well that the idea popped into my head. I haven't smoked since May 2009. Thanks, (b) (6)

Fri 6/12/2009 1:04 PM

Hi,

I've been using your Ariva tabs.

I'm wondering if your product will be grandfathered in under the FDA bill that was passed yesterday.

Basically, I'm asking if I should stock up now before they do something foolish to make these less available.

By the way, by using Arivas, I've been able to keep from smoking for the last 93 days, and that's after 38 years.

I know they're not sold as smoking cessation aids, but they've worked for me.

Much to my amazement, and to the amazement of everyone who knows me :)

Thank you.

(b)
(c)

Tue 12/20/2011 9:50 PM

Sara- I am the Health Promotion Coordinator at a US Army installation in (b) (6) and happened to come across Stonewall at the AAFES Exchange.

Turns out I am having good success with a few soldiers who are attempting to quit dipping, however after some research I discovered AAFES only made a one time purchase without reorder.

I've requested they restock, however there is no guarantee corporate headquarters is interested, so I would also like to know where I can order directly? I found this on amazon with the incorrect product features, etc. but was able to order a couple boxes, however I would be interested in ordering a larger quantity and let the Army pay for it.

http://www.amazon.com/gp/product/B0011W4PZ2/ref=sc_pgp__m_A39MNTHT6DUSRX_12?ie=UTF8&m=A39MNTHT6DUSRX&n=&s=&v=glance

This is a great product- perhaps I could make some noise to promote it's use by the military- everybody seems to be hung up on using Chantix and I would like to steer them away from that.

If you could identify a source for me I would appreciate it.

Wed 4/6/2011 8:11 PM

Dear Star Scientific-

I quite smoking several years ago, as soon as your arriva and stonewall products were available in Texas.

The local stores no longer carry the product and I am desperate. Is there anyone who will ship me a large amount so I can continue to enjoy my addiction? Please let me know. Thanks- (b) (6)

Mon 7/19/2010 6:50 PM

Sara,

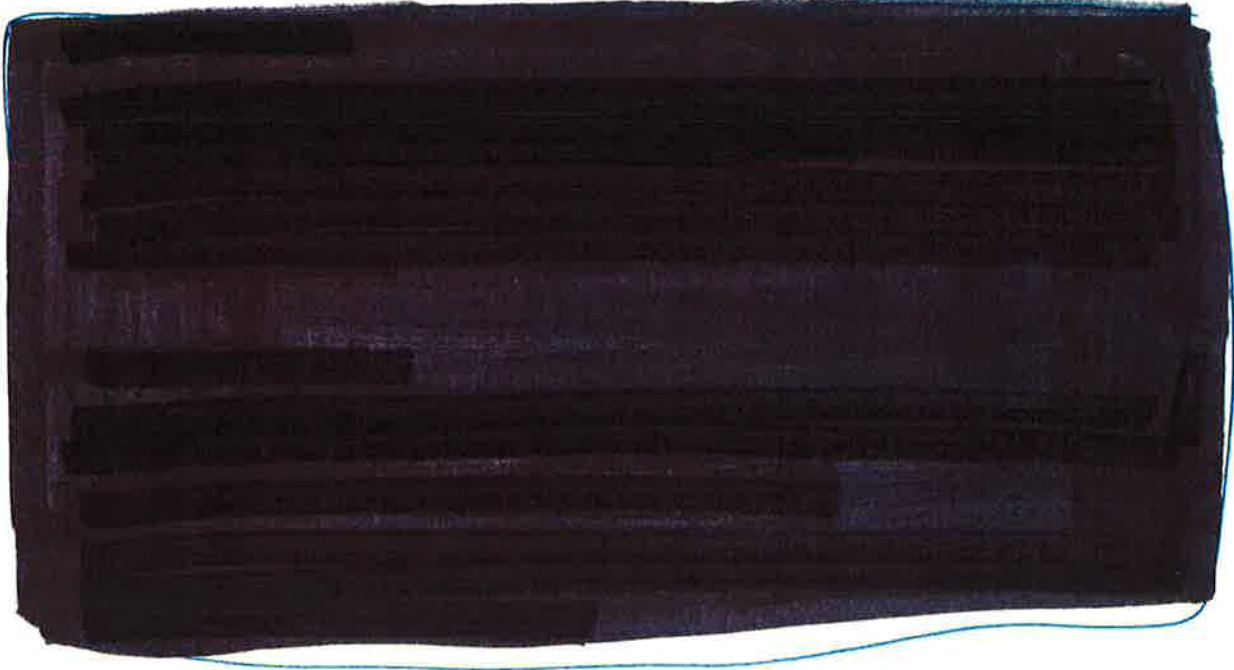
I appreciate your help.

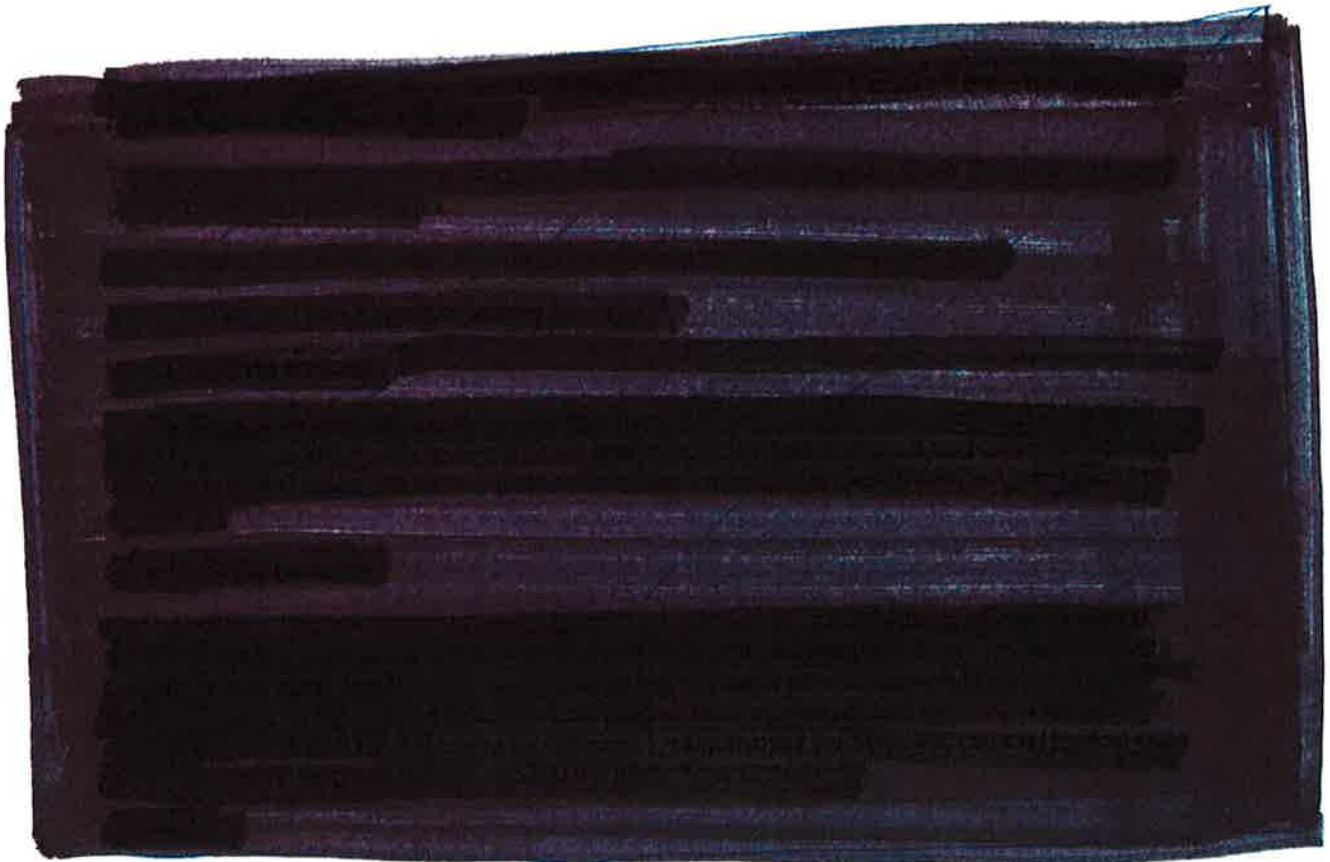
1. Brookville PA in the Choice Tobacco outlet or Sheetz on route 322
2. Dubois PA Sheetz Exit 97 (I-80) or Choice Outlet
3. I travel a lot so any Sheetz along I-80 to State College PA, and any Sheetz along Route I-99 from State College to Bedford PA

Can I call or email Sheetz for you to help the cause? Who or what address would I send too?

Also you guys applied with the Food and Drug admin a while back, how is that going?

I know Stonewall not a safe replacement for smoking. No Doctor or dentist today is going to endorse tobacco replacement but as testimony I just left my peritonitis this morning. The smoking was what caused my problem (and a heart attack too) but your product has not been a problem and my Doctors are seeing marked improvement. In the mean time, my wife isn't bothered with the smell and disgust and I can handle stressful situations without burning my lungs and smelling unprofessional. Thank you. Where was Star 25 years ago and all the other times I tried to quit? So what, it is not a replacement but for the ones that get hooked mentally and physically the odds are 100 times better than any alternative I've found. And you've added some flavor that no gum, tablet or patch provides. OH! SNUS (b) and it's not even close!





September 21, 2006 12:31 AM

Greetings,

I tried your product by taking a chance and ordering it from the catalog that I order my cigarette tobacco from.

I had no intention of giving up the cigarettes, but after using Stonewall I didn't feel like smoking anymore. I've smoked for 40 years. I haven't smoked for weeks.

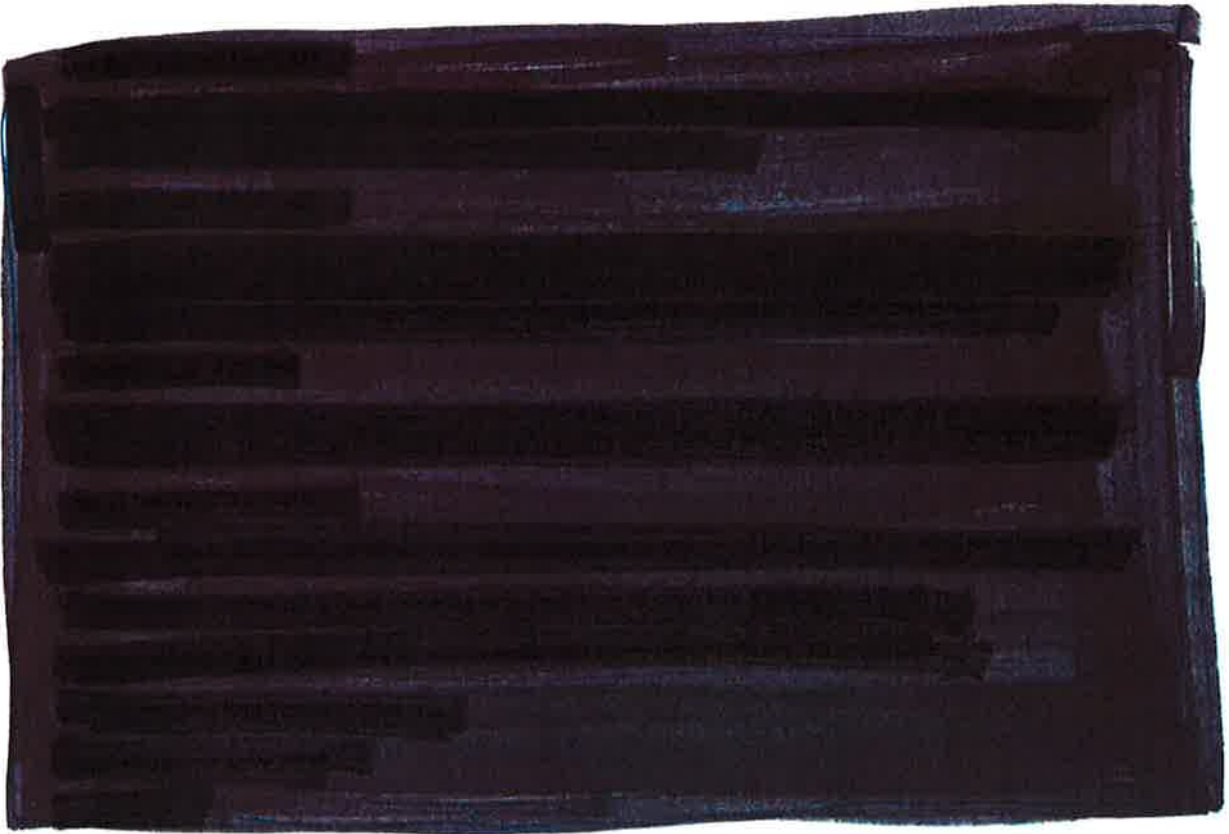
My friends that dip fell in love with your product.

We are in the Youngstown Ohio area and hope you will distribute here soon. We have to mail order now.

Recently I found out that your product was low in TSNA's. What an added bonus.

Thank You and Good Luck..... Ms. Machir





Fri 9/22/2006 11:48 AM

Thank you for the information, but is this true for every state? I live in VA now but am moving to North Carolina...

Ariva helped me stop smoking completely and now I only have a few Ariva "mints" a day - great product!

**Clinical Research Nurse
Cancer Centers of North Carolina**

The Wall Street Journal published an article on September 16, 2006, titled "Should Snuff Be used as a Tool to Quit Smoking?". The author, Kevin Helliker, contacted the company while preparing the article to get information about Ariva. When the article subsequently was published, we were surprised to read about a nurse who was using the product. She subsequently emailed us. We asked her consent last week to share her experience. The following is her story, and her email response to us.

Never mind the fact that I worked as an oncology nurse for over 20 years and knew the risks, never mind the fact that I watched my mother die of lung cancer...I smoked and I knew I was addicted. After almost 35 years of being dependent on cigarettes, I woke up one day knowing just how badly I needed to quit. On that September morning in 2005, I made the decision to quit...again. I had tried the "patch", the "gum", the "lozenges"...all guaranteed to help me reach my goal in the past - and I might add at a hefty monetary rate. Why did I think that morning would be any different?

When I arrived at work that day, I overheard a physician colleague talking about a lecture he had attended, and how impressed he was with the material and research on smokeless tobacco the other physician had reported. I listened with excitement as his enthusiasm rose regarding the information. I immediately found the lecturer and asked to speak with him. He was gracious to see me that day.

I listened to him intently and knew that maybe, just maybe, this method would help me finally quit smoking FOR GOOD. I began using Ariva, a dissolvable smokeless tobacco product, on that date....and never picked up another cigarette again. Whenever I felt the craving, I was able to use this small pellet so discretely that anyone would only think I had popped a mint into my mouth. At first, I used 12 -16 of these small pellets a day. I could tell when the craving and the anxiety began, and just as easily after using the Ariva, I could feel those cravings disappear. I had finally found a method that worked! Now I use perhaps one half of that amount each day.

I'm a HUGE supporter of these dissolvable smokeless tobacco products, both Ariva and Stonewall.

July, 2007



Statement of [REDACTED]

We received the following email on October 19, 2007, from an Ariva® user whose husband was a researcher at Medical College of (b) (6) and had performed early pharmacokinetic testing on the product in 2001. [REDACTED] encouraged his wife, [REDACTED] to try the product, as she was a dependent heavy smoker.

We contacted [REDACTED] and asked her consent to share the text of her email – the following is her story, and her response to our request.

After torturing my body and my lungs with smoking for close to 40 years, I discovered Ariva. I tried stop-smoking medicines but they gave me terrible indigestion. And I still wanted to smoke. Then I tried Ariva. That was two years ago and smoking is absolutely history for me. I have quit before. All smokers out there will know what I mean. It's a pretty fierce addiction. You try to quit but it lures you back. No more. I am NEVER going to smoke another cigarette. When I quit I was on 3 different medicines for breathing difficulties. I used 2 inhalers and a pill and still there were times during the day that I didn't feel like I was getting enough air. Within a week of quitting, I was off of all of the medicines and for the first time in a very long time, I felt like I could breath. Needless to say, my Doctor is ecstatic about it. My pulmonary tests are absolutely perfect now. And the stigma of smoking has disappeared too. I always felt like people were looking down on me for smoking. And I know some of them were. And no more missing a part of a movie because I am dying (really) for a cigarette. No more being frantic on an airplane because I can't smoke. I feel free! Thank you Ariva!

I would be very pleased for you to share my experience with Ariva. Feel free to pass along my phone number and address as well -

[REDACTED]

Ariva & Stonewall Customer Correspondence

-----Original Message-----

From: xxxx
Sent: Friday, September 22, 2006 11:48 AM
Subject: RE: Ariva Sales

Thank you for the information, but is this true for every state? I live in VA now but am moving to North Carolina...

Ariva helped me stop smoking completely and now I only have a few Ariva "mints" a day - great product!

Sent: Thursday, September 21, 2006 4:43 PM
To: Sara Machir
Subject: Re: Stonewall a great product

Greetings,

I guess I never thought you would respond.

I was smoking around 30 cigarettes a day for the past 15 years after weaning myself down from 50 a day the previous 25 years.

I am currently smoke free and using 6 to 7 bits of Stonewall a day.

My friend who dips says he is using 6 to 7 bits a day also.

I am a 52 year old white male. High school grad and college drop out. Blue collar, Vietnam era vet. I was a steelworker 'till the mill closed, and with the children raised, I have been playing bass guitar in rock&roll bands full time for the last 14 years. I never use alcohol and enjoy being with people.

As I said, it was never my intention to stop smoking, but I did. Seeing how you have expressed an interest, I will explain how.

For the past 8 years I have been rolling my own smokes using Stokers #2.

I mail ordered it directly from Stokers as I also needed filters that I could not purchase at the local tobacco shops. They sell filter tubes and this was not my rolling method. I only mention this because I wanted you to know that they (the retailers) were unwilling to carry the filters and may as well be unwilling to carry your product if there is not a strong demand.

I tried Stonewall out of curiosity upon seeing them in the Stokers catalog.

The fact that it was spit free, hard and dissolvable is what attracted me to it. I wear dentures and assumed that moist snuffs wouldn't work well so I never tried them. I tried pouched snuff but after 3 pieces gave up. It's messy.

I seemed that in the morning my nicotine cravings were insatiable. As soon as I put a cigarette out I wanted another. So I started by placing a Stonewall bit in my mouth and smoking the first cigarette of the day. I would then wait until the bit was gone before smoking again. I started skipping the smokes in between bits. Before I knew it, I was down to 3 or 4 cigarettes a day. One upon waking, after lunch and dinner, and one before bed. Soon I didn't feel the need for the bedtime smoke. Shortly after I felt brave and skipped the wake up smoke. Next thing I knew I had gone a whole day without a cigarette. Not really because I felt I had to, but just to see if I could. I told a friend that I hadn't smoked all day and he said that maybe I should try for two days. I

already felt better and thought my singing was better so I went for it. I haven't had a cigarette since.

I'm not coughing and I don't have any phlegm. I feel better and I haven't had to suffer any withdrawal symptoms. I guess this is why I contacted you in the first place. I'm sure that there are going to be people out there that think making and selling any tobacco products is a bad thing. And I'm fully aware that there is no such thing as a safe alternative, however this is the best thing that has happened to me for dealing with my nicotine addiction.

I hope this is helpful to you....Stonewall has been helpful to me...

Again, thanks for the great product..... (b) (6)

P.S. I really think that word of mouth will spread your product. I've got two of my friends ordering it for themselves.

Hope its not inappropriate to mail you now I am no longer Jill's secretary - but I felt I really ought to thank you for the kick start you gave me in attempting to stop smoking. I really do feel the injection came from you and your alternative!

I have been smoke free for nearly 6 weeks, and it really has changed my life, Im playing competitive netball for the Home Office twice a week (b) (6) want me to play for them); swimming 2-3 times a week with my son and only yesterday was asked to join the (b) rounders team to try and win the "Barbados Challenge". So that makes me a "head-hunted" player!!

I had forgotten how much I love sport, competeting and that rush on achieving. I adore running for the train now and catching it. My house is smoke free, my health is improved ten fold, and I cannot understand why I ever smoked. I will never return to it, no matter how stressed I may become with life's punches. I am truly a non-smoker!

I am now helping my two neices to stop smoking as well as my life long best friend. I am a complete convert - and by your helping hand, I am now helping others.

Thank you. Wish I'd done it 30 years ago.

(b) (6)

Sent: Monday, March 27, 2006 7:00 PM

To: Sara Machir

Subject: need to buy your lozenges

I am having trouble finding Ariva lozenges in my area. I quit a 21/2 pack a day habit by using this great product. That was 2 years ago. I want my daughter to quit but can't find the product. Even if I have to buy a carton, I would love to purchase more. Can you help? I live in So. Cal. (San Bernardino). My e-mail address is -----and my phone number is -----

Sent: Thursday, January 12, 2006 7:25 AM
Subject: Another Ariva success story

Sara,

I had a conversation with my sister last night that made me think to write you. Some time ago I gave her some Ariva for a friend of hers in Bellingham Washington who she wanted to get to quit smoking cigarettes. Like most smokers he was reluctant to change. Then he got a diagnosis of Type-2 diabetes, did lots of his own research on the Internet, and got out the Ariva. The Ariva, he says, 'got him over the worst cravings' and he has subsequently moved on to NRT and is staying smoke-free.

You're making a difference.

Sent: Wednesday, September 07, 2005 11:57 PM
Subject: Question about Ariva

Hi folks,

I have been able to get (and stockpile) Ariva hard snuff that seems to be from old stock - being sold by CVS Pharmacy here in Austin. Are you still producing the product?

I have to say after trying several times to quit smoking - I have to admit - I enjoy nicotine. By having your product handy, when I go to bars or out with friends, by having Ariva handy I can actually enjoy an evening at the bar or playing cards with friends without the need to smoke. I have been smoke-free for a year by using Ariva. I feel good that you all have tried to reduce the risk of tobacco usage. I certainly understand the health risks - but by having Ariva handy I can enjoy tobacco on occasion (I use about two boxes a week) without lighting up. My blood pressure is now normal, my breath and my clothes don't stink, and I can enjoy my tobacco.

I don't want to quit. But I don't want to smoke. I want to have a box or two of Ariva. I have friends who keep their eyes out at CVS and have managed to stockpile about a dozen boxes at the moment - I have managed to keep myself supplied for about a year but in a haphazard way. And it's not the FDA, state, federal, or any other group's concern.

Please keep me informed of your progress. I am an adult, I enjoy a legal product, and I am grateful for a product that I can enjoy, I do not inflict second-hand smoke on anyone else, I can use at home, and while it still carries many of the risks associated with tobacco use it is manufactured by a company seeking to reduce those risks. My family grew tobacco for over 100 years in southern Ohio and I appreciate the responsible approach your company tried in providing a safer product.

Good luck - please let me know if I am using the last of a dwindling old stockpile - and if not - you have a satisfied customer in Austin.

To: smachir@starscientific.com
Subject: Requesting information from Public Relations at Star Scientific, Inc

I just wanted to let your company know that I have smoked

cigarettes since I was 12 years old. When I started it was a cool thing to do with friends. We really did not know how bad it could be for us. I am now 44 years old. I have heard and read alot of info from folks that seem to block new ways that come on the market to help folks to stop smoking. I went to my doc to get the lolie pop that had been out, but as soon as i ask he told me that because these people were complaining that kids might get the Pop, the fda pulled it from the market. I wish people would understand that I am an adult and that this pop was intended for me. I keep cherry flavored cough med in in my house but that does not mean that my children will get it. Anyway I have found your product Ariva and guess what I do not smoke anymore. My husband says I smell great and my skin looks better. THANKS (b) (6)

Sent: Wednesday, September 22, 2004 9:49 AM
Subject: RE: Oct. timing

Well, I have to tell you that at the weekend I didnt even buy a packet of cigs at all. (Saved at least £10 min) My parents were over and my father detests smoking, so with extra parental help, I didnt have any cigs - I felt very proud of that Sunday night when I lapsed! Although I lapse sometimes, I most certainly have found they cut my intake by at least 50%. My neice has had a couple and she thought they were the best she had tried!

I have to be honest tho ... I still need a fix in the morning and afternoon at work! But those tablets should be available to all. I quite like them (are they addictive too?). The most impressive result is not lighting up after eating - they really do work!

Thanks - I will persevere

[REDACTED]

FYI, please contact her.

David

-----Original Message-----

From: [REDACTED]

Sent: Friday, August 22, 2003 7:59 AM

To: David Dean

Subject: FW: why wont the ariva people call me back or answer email?????

-----Original Message-----

Sent: Thursday, August 21, 2003 11:54 PM

To: jwilliams@starscientific.com

Subject: why wont the ariva people call me back or answer email?????

Dear sir,

I have tried on NUMEROUS occasions to get a reply from your company. please see the thread below to get a feel for my frustration. I used to be a happy Arive customer....i have quit smoking and completely switched to Arive as a substitute.

The lack of responce has turned from a promoter of Ariva (to family and friends) to a completely frustrated consumer. I hope that this is an oversight....but im really beginning to wonder.

I have a very simple question! NOT a LOT to ask!

sincerely

[REDACTED]

[REDACTED]


-----Original Message-----

From: [REDACTED]
Sent: Sunday, September 15, 2002 4:59 PM
To: ariva@starscientific.com
Subject: Ariva

My friend, (b) (6) has COPD. His lungs are in very bad shape. He coughed and hacked at all hours. He could not walk ten feet without loosing his breath. Finally, he listened and tried Ariva. He has been using it for almost five months. His lungs have improved and the coughing and hacking are almost gone. He can walk across the pasture where my horses are and now can even ride them. His doctor said she has seen a great improvement in his health, and I have too. So, I would like to say thank you for your product.
Thank you, thank you.

Best regards,
[REDACTED]

[illegible]



From: (b) (6)
Sent: Friday, March 14, 2008 11:19 AM
To: Sara Machir
Subject: Happy customer

Sara,

This is a message I rec'd from (b) while I was in London. He is a fellow investment buff and I often write him about the markets, but in this case got another unsolicited endorsement of Stonewall. It was useful to me as I had just met with UK colleagues for a discussion about whether health groups should recommend that SLT be legalized in the EU. So I passed (b) message around I frankly do not see how any self-described 'health advocate' can deny access to a massively less hazardous alternative to cigarettes to people like (b)

Dave

From: [REDACTED]
Sent: Tuesday, March 11, 2008 5:38 PM
To: (b) (6)
Subject: Re: Bi-polar markets

bi-polar is the only description! It's really just nuts. I notice that Antrim went through the roof today. I haven't had time yet to check on whether there was news.

On the non-smoking front...I continue to be amazed at how well the Stonewalls head off my cravings. I'm now into my second week. If you assume that I was smoking 25 cigs per day and am now using, instead, about 8 Stonewalls per day...I think that anyone should be able to figure out that this product is having a significant positive influence on my health. I find that it just takes the edge off enough for me to forget about my craving while I really do enjoy the flavour of the wintergreen Stonewalls.

This is a very pleasant way to quite smoking...

I wonder if any of the people who are in public policy ever actually bother to consult smokers as to their needs/wishes?

I was thinking that the Stonewall people could do a campaign with the phrase "health and wealth" somewhere in there....given that it can be used as a quit smoking product and that the price of cigs really adds up over time!

Take care...have a great trip back to snowy Ottawa!



[REDACTED]

Sara Troy Machir
Vice President, Communications & Investor Relations
Star Scientific, Inc.
301-654-8300

From: [REDACTED]
Sent: Saturday, August 16, 2008 1:16 AM
To: Information - Star
Subject: Longtime user trying to quit

My names is (b) (6) and grew up in the US but now living in India. I started chewing when I was 13 years old. Now I am 38. So that is 25 years and everyday straight. In addition, no gum disease or deformation to my teeth. Back then I only had 2 choices of tobacco to choose from...Copenhagen and Skoal.

Well, Reason I am writing this is to truly thank you for your Stonewall product. I have been chewing Kodiak ever since it came out. I used to chew a can a day. Now with Stonewall I may use Kodiak 1 or 2 times a day. Stonewall has helped me wean out the use of Kodiak. In a couple of weeks I will only be using Stonewall. No more chewing tobacco. Take It from a 25 year veteran on chewing tobacco that the product really works. I would not give a See below to take the time to write this if it did not. For the first time in 25 years I actually went 8 days without any tobacco and only used the Stonewall product. Believe it or not that I did not experience any side effects from the absence of tobacco. I believe the Stonewall had to do with that even though it is not as strong as Kodiak.

So thanks again for Stonewall. I truly appreciate it and so does my family. My wife is so happy of my progress. And for anyone who reads this I swear on my eyes that it truly is a great alternative to chewing tobacco.

Thanks again Stonewall,

In accordance with 21
C.F.R. 20.10, the above
word has been deleted

The Only Thing Necessary For The Triumph Of Evil Is For Good Men To Do Nothing...

Edmund Burke

th	418	7/17/2002	PA	that he loved the product and wanted the company to know that it has helped him stop smoking because he us to smoke 2 1/2 packs of camels cig a day for 43yrs. And with this product he has given up smoking all together.
la	132	1/31/2003	NH	Re: info about Ariva b/c she is trying to quit. She had tried the patch, but it didn't work for her. She now understands that Ariva is not a smoking cessation product, but she claims that it has already helped her to quit. She is a satisfied customer!
ral	145	3/25/2003	OH	M. wanted to know how much nicotine is in each cigaret - he used Ariva to stop smoking cigars several months ago, then relapsed, so he is again using Ariva to avoid cigar smoking. Purchases the product at a local CVS. Finds the product refreshing.
	167	8/8/2003	VA	had been using Copenhagen for 22 years (first fine cut, then long cut), and said that this is the first product that has enabled him to stop using Copenhagen. He has had one graft, and he needs another (gum tissue, I believe). He wanted to k
	168	9/8/2003		Smoked three packs per day - has successfully quit for eight weeks. Wanted to know how much nicotine was in Ariva and how much tar and carbon monoxide. Informed her that Ariva was a tobacco product not a cessation product. She likes Ariva and said that
	174	11/24/2003	NY	Would not give name or number. Student that has recently moved from GA to NY and has quit smoking using Ariva. In GA Ariva was \$1.99 (\$1.52 on sale) and in NY it \$5.00 a box. He feels like he's being taken advantage of and wanted to order from the compa
	192	4/6/2004		Ariva - Chew for 20 years - Skool. Quit for 2 days using Ariva. Uses three per day. Wanted to know how much nicotine was in one ariva compared to a pinch of skool. Was trying to reduce his level of nicotine.
	198	5/19/2004		Ariva - Quit smoking and is now "addicted to ariva". Wanted to know the percent of tobacco per place and how much nicotine there is per piece compared to the gum.
	218	12/10/2004		Would not give her information. Quit smoking after 50 years and has found Ariva helpful. She wanted information on how much nicotine is in Ariva and where she could purchase it. Gave her a local Rite Aid Address and VAFCO info.
	206	4/26/2002	TX	He hasn't had a cigarette in 2 weeks and really likes Ariva. He wanted to know ideally when he can use the product. I told him in places where it was not appropriate to smoke, such as, on airplanes, restaurants, etc....
	532	8/16/2003	MO	comments: have aided him in stop smoking and has been great for his asthma. wanted to know where to purchase Ariva on MO and info was given
	1382	2/14/2003	CA	Re: Where to purchase Ariva. He quit smoking 2 months ago and has been using Ariva since then. He needs to buy more and there is not a convenient location. His zip code was entered in the Store Locator and a Florida address popped up. In addition to, m
	158	7/10/2003	TX	Customer has brother in Hayward, CA. wanted to know if there were product in that location. had smoked for 40 years, was up to 2-3 packs per day. She stopped smoking one year ago, used Ariva to get through. They have been very helpful. She is n
	1706	10/3/2003	VA	Tammy was an Ariva user when they first came out. Quit smoking by using Ariva, but she's now smoking again because she can't find Ariva in stores. Gave her a few store locations in her are from the store locator and also gave her the number to VAFCO. S
	187	3/1/2004	WA	Ariva - Ariva not in stores. Helped her quit smoking. 2 packs a day for 35 years, now 5 or 6 Ariva per day.
	2255	2/11/2005	NC	Could not find a location to purchase. Gave her one location and VAFCO number. Ariva helped her quit smoking bu she started back up again.

Not complete - Qui were from Call log for 2 +

[REDACTED] [REDACTED]

SK/A

Stated 50 yrs - Last in
3 month

[REDACTED]

(

I am not sure where this information
is coming from, and I don't
know the date either

DATE	NAME	STATE	ZIP	ADDRESS	PHONE	EMAIL	STATUS	REMARKS
1/11/2007	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
1/11/2007	[REDACTED]	IN	46033	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
7/24/2007	[REDACTED]	Parkas	VA	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
7/26/2007	[REDACTED]	Whitman	TX	76012	[REDACTED]	[REDACTED]	[REDACTED]	Male
7/30/2007	[REDACTED]	Adair	TX	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
7/7/2007	[REDACTED]	GA	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
7/13/2007	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
8/1/2007	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
8/6/2007	[REDACTED]	Little Falls	NH	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
8/6/2007	[REDACTED]	NE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
8/8/2007	[REDACTED]	Houston	TX	77279	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
8/16/2007	[REDACTED]	Austin	TX	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
8/22/2007	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
9/4/2007	[REDACTED]	TN	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
9/18/2007	[REDACTED]	RI	02885	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
10/13/2007	[REDACTED]	Raleigh	NC	27607	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
11/7/2007	[REDACTED]	[REDACTED]	26001	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location
11/7/2007	[REDACTED]	Blacksville	OH	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Purchase Location

[illegible]

Sara Machir

From: [REDACTED]
Sent: Tuesday, April 16, 2002 7:47 PM
To: mail@starscientific.com
Subject: Ariva

A friend of mine gave me a couple of your cigaletts, when I tried them I was impressed with the way they take the craving away for a regular cigarette. When I tried to purchase them I was told they were only a promotional item and not available for purchase. I would like to know if I can order some directly from you, I plan to use them as a tool to help me quit smoking. I understand they are a tobacco product also, but the effect lasts quite a while and I really think they can help me to give up smoking!

Thanks!

(b) (6)

Sara Machir

> -----Original Message-----

> From: [REDACTED]

> Sent: Friday, September 27, 2002 12:32 PM

> To: ariva@starscientific.com

> Subject: Ariva

>

>

> Hello!

> I was recently introduced to your product while traveling.... I
> live in Salem, Oregon. Upon returning home, I found your store
> locator, but have since discovered our local Rite-Aids only stock a
> couple of boxes on an occasional

>
> basis. Any idea when Ariva might be more readily available in my area?
> By the way, Ariva is a wonderful ideal. It is my answer to many social
> situations I find myself in, and I find that I actually prefer to use
> Ariva as opposed to smoking on a regular basis.... Thank you!

>
> (b) (6) [REDACTED]
> [REDACTED]
> [REDACTED]
> [REDACTED]
> [REDACTED]
> [REDACTED]
> [REDACTED]

Sara Machir

From: [REDACTED]
Sent: Wednesday, November 19, 2003 6:13 PM
To: smachir@starscientific.com
Subject: Ariva

I took this address from Star Scientific's Web Page and I am trying to find out where I can purchase Ariva locally (Northern California) I first heard of it and purchased it three weeks ago at the Oakland (Calif.) international airport, and have since tried to find it in the general market place - no luck. I also asked my pharmacist to see if he could get information for me, also No luck. Please send me information regarding this product and its availability on the general market.

Thank you for your kind attention. P.S. I am an elderly widow who has been smoking since I was 13, and do NOT plan to stop now, however, I found Ariva extremely helpful on a recent VERY long plane trip, and I have since used it with some satisfaction in a couple of other "No Smoking" situations. Again, any further information you can send me will be most appreciated. I will be happy to provide my address and phone number if it would be helpful. [REDACTED]

Sara Machir

From: [REDACTED]
Sent: Thursday, May 15, 2003 11:24 AM
To: Smachir@Starscientific.com
Subject: Ariva
Importance: High

Sara,

My wife, (b) (6) is visiting me in the office today, she left her Ariva's at home would you know where we could purchase these in NYC zip code 10010. They help her get through the day especially here in NYC.

Thanks,
(b) (6)

Sara Machir

From: [REDACTED]
Sent: Tuesday, April 15, 2003 2:34 AM
To: smachir@starscientific.com
Subject: ARIVA

To Whom might listen:

I started using Ariva in June of 2002 by July I was off Cigarettes all together, and now I can't get the Ariva any where, you people can't play this game on me I was a two pack aday smoker for 30yrs. and found the one way that worked for me. then you cut me off, I'm mad and hurt that you can do this to me again. So now what am I supposed to do? Go back to smoking? start using Commit at three times the cost this is like getting hooked on a drug and now the dealer raises the price cause he knows you gotta have it. Thanks for the false hope.

=====

Keep yer powder dry&your flint sharp
Y.M.O.S.

[REDACTED]

Do you Yahoo!?
The New Yahoo! Search - Faster. Easier. Bingo <http://search.yahoo.com>

Sara Machir

From: [REDACTED]
Sent: Thursday, April 25, 2002 2:52 PM
To: 'smachir@starscientific.com'
Subject: Ariva cigalett mints

Dear Ms. Machir:

(b) (6) Where can Ariva cigarette mints be purchased in the Richmond/Hanover County, Virginia area? My son, a student at (b) (6), has purchased them in the Radford, Virginia area and has successfully quit smoking for a month. He is currently reducing the quantity of mints being used as a substitute and is looking forward to being "nicotine free." I would like to purchase them for my daughter, a student at (b) (6), and for my husband, a cigar chain smoker.

Thanks for your assistance in this matter.

(b) (6)

Sara Machir

From: [REDACTED]
Sent: Thursday, February 07, 2002 1:35 PM
Subject: Re: RE: Ariva

Thanks so much. I'm still using the Ariva, and still enjoying them. I haven't been able to quite smoking, but your product gives me hope.

(b) (6)

You wrote:

[REDACTED]

--Original Message-----

Sara Machir

From: [REDACTED]
Sent: Monday, April 08, 2002 10:00 AM
To: (b) (6)
Cc: smachir@starscientific.com
Subject: RE: Ariva

Hi (b) (6)

My intent has been to use ARIVA as an aid to stop smoking completely. ARIVA was helping me cut back. The unavailability of the product, up to now, has been a hindrance. I haven't used them for several weeks because I didn't want to make the trip to pick some up.

I did notice some stomach bloating when I used the product. I may have sucked on too many throughout the day. I enjoy the longevity of ARIVA. The flavor does seem satisfy the craving and helps alleviate tension when I am not smoking at all.

The last email we received said they would be in the Minyard's stores in the area. When [REDACTED] called, they weren't there and the store clerk didn't know when they may be in stock.

Hopefully they are more accessible now



Sara Machir

From: [REDACTED]
Sent: Thursday, May 15, 2003 4:29 PM
To: Sara Machir
Subject: RE: Ariva

Importance: High

Sara,

I use them at work also but still need cigarettes after meals and first thing in the morning.
I can't stomach the Ariva first thing in the morning, do you have any suggestions?

E



Sara Machir

From: [REDACTED]
Sent: Sunday, July 14, 2002 10:23 AM
To: Sara Machir
Subject: Re: Ariva

Sara,

I have been very selective about taking this product due to my pregnancy. I can tell you that I have used it three times in one day and now I'm down to one per day although my goal is to eliminate the product altogether this week.

I have taken it mostly in the morning, during my work schedule hours. When the stress is highest or when I'm really See below. I have only taken it for about a week but I tell you it has helped because I have quit once before and it was a real See. My mood swings aren't as bad and I'm more calm. There is a definite difference not having all those chemicals in your body.

I have been smoking religiously for about 12 years and I think most of the determination to quit is due to the baby. I am still craving cigarettes and God knows I would love one now. The real test is to continue the absence of the dastardly habit after the baby is born.

I believe the control cigarettes have over people is both physical and psychological. Americans need bad habits...we are all addicts in a sense.

In accordance with 21 C.F.R. 20.10, the above words have been deleted.

Hope this is helpful, I'll let you know how I do this week.

I will recommend your product, especially to my mother.



Sara Machir

From: [REDACTED]
Sent: Wednesday, January 01, 2003 1:33 PM
To: Sara Machir
Subject: RE: Ariva availability

Dear Sara:

Thanks for your reply. I'm sorry to tell you that of the first two stores on your list, one, C Mart on W. 24th St., no longer carries Ariva, and the owner of the other, Babalu Cigar Co., says he will no longer carry it when their current supply runs out. But Babalu is where I currently find it. The other stores on your list are inconveniently located for me, but I'll check into them and Albertsons as well. Also, the area code in Austin is 512, so I don't think the telephone numbers you list with the stores is correct.

Another communications problem you have is the perception that Ariva is no longer being made. More than one retailer who formerly sold the product told me this. One even told me Star Scientific, "is out of business." Who is repping the product down here?! He/she is not helping you.

It was at one of these retailers that no longer carries the product that I was first introduced to Ariva via a free sample. I must say that, at the time, I tried it and found it to be a novelty and did not think it would be useful for me. What motivated me to seek Ariva out again was that I recently had a pretty severe case of bronchitis brought on by allergies. I didn't want to smoke until I was completely well, but at the same time, I still wanted to enjoy tobacco. Ariva was the perfect answer.

Now that I can smoke again, I am still using Ariva to moderate my typical cigarette intake of 5-12 American Spirit Ultralight cigarettes/day. While I recognize that no tobacco product is as safe as not using tobacco at all, I find that using Ariva offers the tobacco satisfaction I want without some of the negative physical aspects I experience from smoking. For instance, I'm a runner and a racquetball player, and I find that on days when I have smoked, it is harder to catch my breath when I participate in sports. With Ariva, I notice no such problems. So on days when I run or play racquetball, I will use Ariva instead of smoking before the activity, and only smoke afterwards.

In my household, we do not smoke indoors because we do not like the lingering smell it leaves, which can make smoking in inclement weather a drag. With Ariva, I can enjoy tobacco indoors, at any time and in any weather. Also, I work from home as a writer, and another thing I like about Ariva is that I don't have to interrupt my work when I want tobacco enjoyment; I can use Ariva right at my desk.

One thing using Ariva has made clear to me is that the satisfaction I get from tobacco and the satisfaction I get from the activity of smoking are distinct. I do enjoy smoking, but am concerned about the immediate and long-term health effects. With Ariva, I feel I can mitigate the negative effects of *smoking* tobacco by smoking less, while still enjoying tobacco.

In answer to your inquiry, I've been smoking for about 20 years. I've quit smoking many times for periods up to 5 years in that span. Currently, I do enjoy smoking tobacco every day, but because of the well-known health problems associated with smoking tobacco, I consciously moderate my use. I feel that Ariva is a helpful product in this regard.

Probably more than you wanted to know, but I hope you find some of this info helpful.

-----Original Message-----

From: [REDACTED]
Sent: Sunday, September 07, 2003 4:14 AM
To: ariva@starscientific.com
Subject: Ariva

I just wanted to say thanks for Ariva. I have been wanting an alternative to cigarettes for a long time but just didn't like copenhagen, skoal, or any other smokeless product until I found out about Ariva. I have been using Ariva for 9 months without smoking. Arriva is the best alternative around.

Thanks,
[REDACTED]

Feb 3, 2010

to whom it may concern;

My name is (b) (6) and I am writing to you to let you know that the F. D. A. should get their facts together before they are worried about the packaging colors of Ariva and Stone all products. I have used them since October 2009. I want you to know that this product has allowed me to work as a nanny for days at a time. If I didn't have this product I couldn't take these jobs as I am a smoker. I also smoke outside. I no longer have to freeze to death while smoking outside. I say a big

THANK YOU! and please continue making these products.

Also 99% of any store that sells tobacco products - the products have to be given to the consumer because they are behind the counters. Even at Wal-Mart! So I feel the F. D. A. doesn't really know all the facts. Because you have to produce an I. D. to purchase them.

Thank you for your products.

Sincerely,

E-mail address

[REDACTED]

[REDACTED]

Sara Machir

From: [REDACTED]
Sent: Monday, March 17, 2003 6:52 PM
To: Sara Machir
Subject: Re: Arriva

Sarah,

Thank you for your quick reply. My smoking has most certainly changed since I discovered Arriva. I have never been able to give up cigarettes, even with nicotine gum and other aids. With a few pieces of Arriva daily I have been able to go smokeless. It has allowed me to become an occasional smoker. I fully realize that Arriva is not risk free, however with a family history of emphysema, it represents a more healthy alternative for me. As a microbiologist it has also improved my image with my colleagues.

Thank you.

[REDACTED]